



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1100, 1140, and 1143

[Docket No. FDA-2014-N-0189]

RIN 0910-AG38

Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; correction.

SUMMARY: The Food and Drug Administration (FDA or we) is correcting the preamble to a proposed rule that appeared in the Federal Register of April 25, 2014. That proposed rule would deem products meeting the statutory definition of "tobacco product," except accessories of a proposed deemed tobacco product, to be subject to the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). The Tobacco Control Act provides FDA authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and any other tobacco products that the Agency by regulation deems to be subject to the law. Option 1 of the proposed rule would extend the Agency's "tobacco product" authorities in the FD&C Act to all other categories of products, except accessories of a proposed deemed tobacco product, that meet the statutory definition of "tobacco product" in the FD&C Act. Option 2 of the proposed rule would extend

the Agency's "tobacco product" authorities to all other categories of products, except premium cigars and the accessories of a proposed deemed tobacco product, that meet the statutory definition of "tobacco product" in the FD&C Act. FDA also is proposing to prohibit the sale of "covered tobacco products" to individuals under the age of 18 and to require the display of health warnings on cigarette tobacco, roll-your own tobacco, and covered tobacco product packages and in advertisements. FDA is taking this action to address the public health concerns associated with the use of tobacco products.

The document published with several technical errors, including some errors in reference numbers cited in section VII.B. of the document. This document corrects those errors. We are placing a corrected copy of the proposed rule in the docket.

DATES: The proposed rule published April 25, 2014 (79 FR 23141) is corrected as of [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Gerie Voss, Office of Regulations, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850-3229, 877-287-1373, CTPRegulations@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is correcting the preamble to the April 25, 2014 (79 FR 23141), proposed rule entitled "Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products." We are correcting references 2, 92, and 151-157 in the reference list and in section VII.B. We are also placing a corrected copy of the proposed rule in the docket.

In FR Doc. 2014-09491, appearing on page 23141 in the Federal Register of Friday, April 25, 2014 (79 FR 23141), FDA is making the following corrections:

1. On page 23165, in the first column, "(Refs.154, 155, and 156)" is corrected to read "(Refs. 154, 154A, and 155)."
2. On page 23165, in the first column, "(Ref. 155)" is corrected to read "(Ref. 154A)."
3. On page 23165, in the second column, "(Ref. 156)" is corrected to read "(Ref. 155)."
4. On page 23165, in the second column "(Ref. 159 at 11)" is corrected to read, "(Ref. 158 at 11)."
5. On page 23165, in the second column, "(Ref. 159 at 12)" is corrected to read "(Ref. 158 at 12)."
6. On page 23197, in the third column, reference 2 is corrected to read: "2. Arrazola, R.A., N.M. Kuiper, and S.R. Dube, "Patterns of Current Use of Tobacco Products Among U.S. High School Students for 2000-2012--Findings From the National Youth Tobacco Survey," Journal of Adolescent Health, 54:54-60, 2013."
7. On page 23200, in the first column, reference 92 is corrected to read: "92. Cobb, C.O., K. Sahmarani, T. Eissenberg, et al., "Acute Toxicant Exposure and Cardiac Autonomic Dysfunction From Smoking a Single Narghile Waterpipe With Tobacco and With a 'Healthy' Tobacco-Free Alternative," Toxicology Letters, 215:70-75, 2012."
8. On page 23201, in the second column, the second reference 151 is corrected to read: "152. Portillo, F. and F. Antoñanzas, "Information Disclosure and Smoking

Risk Perceptions: Potential Short-Term Impact on Spanish Students of the New European Union Directive on Tobacco Products," European Journal of Public Health, 12:295-301, 2002.”

9. On page 23201, in the second column, reference 152 is corrected to read: "153. Hammond, D., G.T. Fong, R. Borland, et al., "Effectiveness of Cigarette Warning Labels in Informing Smokers About the Risks of Smoking: Findings From the International Tobacco Control (ITC) Four Country Survey," Tobacco Control, 15(Supp III):iii19-iii25, 2006."
10. On page 23201, in the second column, reference 153 is corrected to read: "154. Fischer, P.M., J.W. Richards Jr., E.J. Berman, and D.M. Krugman, "Recall and Eye Tracking Study of Adolescents Viewing Tobacco Advertisements," Journal of the American Medical Association, 261(1):84-89, 1989."
11. On page 23201, in the third column, reference 154 is corrected to read: "154A. Krugman, D.M., R.J. Fox, J.E. Fletcher, et al., "Do Adolescents Attend to Warnings in Cigarette Advertising: An Eye-Tracking Approach," Journal of Advertising Research, 34(6):39-52, 1994."
12. On page 23201, in the third column, reference 157 is corrected to read: "156. Truitt, L., W.L. Hamilton, P.R. Johnston, et al., "Recall of Health Warnings in Smokeless Tobacco Ads," Tobacco Control, 11(Supp II): ii59-ii63, 2002."
13. On page 23201, in the third column, reference 156 is corrected to read: "157. MacKinnon, D.P. and A.M. Fenaughty, "Substance Use and Memory for Health Warning Labels," Health Psychology, 12(2):147-150, 1993."

Dated: May 21, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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